

Food and Drug Administration  
Washington DC 20204

Patrick Mooney  
Supernutrition Life-Extension Research, Inc.  
2565 Third Street  
San Francisco, California 94107

April 18, 1995

Re: Nutritional Support Statement Notification

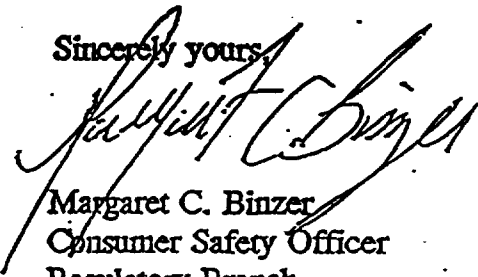
Dear Mr. Mooney:

This acknowledges receipt on March 10, 1995, of your letter, dated March 2, 1995, notifying the Food and Drug Administration (FDA) that your Opti-Packs dietary supplement, a multi-vitamin/multi-mineral daily dietary supplement in packets, is being marketed with a statement of nutritional support on its label or in its labeling.

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), a manufacturer must notify FDA no later than 30 days after the first marketing of a dietary supplement product that bears a nutritional support statement on its label or in its labeling. Pursuant to the act, a manufacturer of such a product must have substantiation that the nutritional support statement is truthful and not misleading. In addition, the nutritional support statement must include, prominently displayed and in bold face type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

No action on the part of FDA is required before a manufacturer can market a dietary supplement product bearing a nutritional support statement on its label or in its labeling. While the act requires that certain information appear on the label of a dietary supplement in conjunction with such statements, FDA does not approve them. This letter serves only to acknowledge the receipt by FDA of your notification.

Sincerely yours,



Margaret C. Binzer  
Consumer Safety Officer  
Regulatory Branch  
Division of Programs  
and Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

975-0162

ACK 1  
Binzer